

KCC 4979
K-C 19,378A
PATENT

REMARKS

After entry of this Amendment A, claims 1-59 will be pending. Claims 11 and 42 have been withdrawn as directed to a non-elected invention. Applicants reserve the right to file divisional applications directed to these non-elected claims.

Applicants have amended claims 1 and 33 to replace the tradename with the INCI name for the dispersing agent. Claim 1 was amended to correct typographical errors. Support for the amendment to claim 33 can be found in original dependent claim 14 and in Dow Corning Emulsifier Products Overview (submitted as Exhibit A). No new matter has been added by these amendments. Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of Claim 33 Under 35 U.S.C. §112, Second paragraph

Reconsideration is requested of the rejection of claim 33 under 35 U.S.C. §112, Second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 33, as originally filed, contains the trademark/trade name Dow Corning 5329. As such, the Office states that the scope of claim 33 is therefore uncertain since the trademark or trade name cannot be used properly to identify any particular material or product.

Applicants have amended claim 33 to replace the tradename Dow Corning 5329 with the INCI name PEG-12 dimethicone. Support for the amendment can be found in original dependent claim 14 and in Dow Corning Emulsifier Products Overview (submitted as

KCC 4979
K-C 19,378A
PATENT

Exhibit A).

As claim 33 has been amended, the rejection of claim 33 under 35 U.S.C. §112, Second paragraph should be withdrawn as moot.

2. Rejection of Claims 1-4, 8-10, 12-13, 15-16, 25-31, 34-35, 39-41, 43-45, 52-54, and 57-59 Under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-4, 8-10, 12-13, 15-16, 25-31, 34-35, 39-41, 43-45, 52-54, and 57-59 under 35 U.S.C. §102(b) as being anticipated by Krzysik (U.S. 5,869,075).

Claim 1 is directed to a moisturizing and lubricating composition comprising from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) of an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. No more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature. At least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Krzysik ('075) discloses tissue products comprising a hydrophilic composition for softening the tissue. The composition comprises from about 30 to about 90 weight percent of a hydrophilic solvent, from about 10 to about 50 weight percent of high molecular weight polyethylene glycol, from about 5 to about 40 weight percent of a fatty alcohol (e.g., C₁₄-C₃₀), and from about 0.01 to about 20 weight percent oil

KCC 4979
K-C 19,378A
PATENT

soluble/dispersible or lipophilic materials. The composition has a penetration hardness of from about 5 to 360 millimeters and a melting point of from about 30°C to about 70°C.

Significantly, Krzysik fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

As noted in the specification of the present application, liquid components of the moisturizing and lubricating compositions are important in that they provide plasticity and help avoid products that are too hard, brittle, or flaky. However, compositions that contain a high proportion of components that are liquid at room temperature are more difficult to process. Furthermore, if the composition contains too high a proportion of liquid components, the liquid components of the composition may migrate away from the surface of the substrate to which the composition is applied, and into the matrix of the fabric of the substrate. It is thus important that the compositions comprise a certain percentage of components that are solid at room temperature. In particular, the solid components, such as the immobilizing agents, provide a network that is capable of supporting the liquid components within it and, therefore, preventing their migration through the substrate. If the solid portion of the composition is too small, the network may be overwhelmed by the large liquid portion, and the solids portion may be unable to support the liquids in the network. See Specification at ¶68. To address

KCC 4979
K-C 19,378A
PATENT

this problem, the compositions of the present invention comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature.

There is nothing in Krzysik stating that the compositions disclosed therein should comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature, no recognition of the advantages of such a composition, and nothing to suggest that the compositions of Krzysik inherently (i.e., necessarily) have such a makeup.

It appears that the Office is assuming that these limitations are inherent in Krzysik. Specifically, with reference to claims 28-30 and 57-59, the Office states that although the prior art does not explicitly recite this property, the prior art will have the same properties since the prior art and the instant claims are the same. Furthermore, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.¹ Applicant asserts, however, that this is an improper assumption.

For example, Krzysik states that the compositions disclosed therein comprise from about 30 to about 90 weight percent of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature, as one example of a suitable hydrophilic solvent. See Krzysik at col. 3, ln. 7-9. The compositions of Krzysik may thus comprise more than 50% by

¹ Office action dated October 24, 2006 at page 5.

KCC 4979
K-C 19,378A
PATENT

weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature). The compositions of Krzysik can thus not be said to inherently (i.e., necessarily) comprise no more than about 50% (by weight) of components that are liquid at room temperature.

Furthermore, it appears the Office has assumed that the limitation "at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C,"² is inherent in Krzysik. This, however, is also an improper assumption.

Krzysik simply states that the compositions disclosed therein have a melting point of from about 30°C to about 70°C. This, however, does not mean that it is inherent that at least about 85% (by weight) of the components of the compositions form a single phase at the composition's melting point. The Krzysik reference defines "melting point" as "the temperature at which the majority of the melting occurs, it being recognized that melting actually occurs over a range of temperatures" (see Krzysik, col. 2, ln. 37-39). The disclosure in Krzysik of the melting point of the compositions thus merely means that the majority of the composition has melted at that temperature; there may, however, still be portions of the composition that have not melted (i.e., solid portions) in the composition, even at the melting temperature. Thus, it cannot be assumed that at least about 85% (by weight) of the components of the compositions will form a single phase at the composition's melting point. Krzysik fails to disclose, either explicitly or

² As noted in the specification, compatibility of the composition is important for providing a composition that is easily processable and stable (see

KCC 4979
K-C 19,378A
PATENT

inherently, compositions wherein at least about 85% (by weight) of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C.

Additionally, we note that the specific formulations set forth in the Examples of Krzysik either lack entirely one of the components of the composition of claim 1 and/or comprise amounts of one or more component that falls outside of the claimed ranges. For example, claim 1 requires the composition to comprise from about 1% (by weight) to about 20% (by weight) of a humectant. However, the formulations set forth in Examples 1-8 and 11-15 of Krzysik all comprise more than 20 wt.% humectants. In particular, we note that glycerin, propylene glycol, and hydrogenated starch hydrolysates may all act as humectants (see Specification, ¶61). However, the total amount of glycerin, propylene glycol, and/or hydrogenated starch hydrolysates exceeds 20 wt.% for all the formulations set forth in Examples 1-8 and 11-15 of Krzysik.³

In this regard, Applicant notes that the Office has stated that the compositions of Krzysik may comprise propylene glycol, which is a compatibilizing agent. While it is true that propylene glycol is a suitable compatibilizing agent (see Specification, ¶66), propylene glycol, as noted above, is also listed as a suitable humectant (see Specification, ¶61). As such, when determining the total amount of humectant in the compositions set forth in the Examples of Krzysik, the amount of propylene glycol in the compositions should also be considered.

As stated in M.P.E.P. §2131, a claim is anticipated only if each and every element as set forth in the claim is found,

Specification ¶70; see also Specification ¶65 for a discussion of the importance of having a compatible composition).

KCC 4979
K-C 19,378A
PATENT

either expressly or inherently described, in a single prior art reference. Since Krzysik fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 1, Krzysik fails to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Krzysik reference.

Claims 2-4, 8-10, 12-13, 15-16, and 25-30 depend directly or indirectly from claim 1. As such, claims 2-4, 8-10, 12-13, 15-16, and 25-30 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 31 is similar to claim 1 and further requires the emollient to be a silicone, and additionally, requires the composition to comprise a dispersing agent. As the Krzysik reference fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 31, Krzysik fails to disclose each and every limitation of claim 31. As such, claim 31 is novel over the Krzysik reference.

Claims 34-35, 39-41, 43-45, 52-54, and 57-59 depend directly or indirectly from claim 31. As such, claims 34-35,

³ Applicant notes that the formulations set forth in Examples 9 and 10 of

KCC 4979
K-C 19,378A
PATENT

39-41, 43-45, 52-54, and 57-59 are patentable for the same reasons as claim 31 set forth above, as well as for the additional elements they require.

3. Rejection of Claims 1-4, 8-10, 12-13, 15-17, 21-22,
25-31, 34-35, 39-41, 43-46, 50-54, and 57-59 Under 35 U.S.C.
§102(b)

Reconsideration is requested of the rejection of claims 1-4, 8-10, 12-13, 15-17, 21-22, 25-31, 34-35, 39-41, 43-46, 50-54, and 57-59 under 35 U.S.C. §102(b) as being anticipated by Tyrell et al. (U.S. 2002/0120241).

Claim 1 is discussed above.

Tyrell et al. ('241) disclose skin barrier enhancing compositions that may be used in connection with absorbent articles. The compositions may comprise from about 10 to about 90 weight percent hydrophilic solvents, from about 10 to about 90 weight percent high molecular weight polyethylene glycols, from about 1 to about 40 weight percent fatty alcohols, from about 1 to about 40 weight percent fatty acids, and from about 0.1 to about 20 weight percent anionic (or decoupling) polymers. The compositions may further optionally comprise from about 1 to about 10 weight percent emulsifying surfactants, from about 0.1 to about 30 weight percent natural fats or oils, from about 0.1 to about 10 weight percent sterols, from about 0.1 to about 10 weight percent emollients, from about 1 to about 20 weight percent viscosity enhancers, and/or from about 0.5 to about 10 weight percent rheology modifiers. The compositions have a penetration hardness of from about 5 to about 365 millimeters and a melting point of from about 32°C to about 100°C.

Krzysik do not appear to comprise any humectants.

KCC 4979
K-C 19,378A
PATENT

Claim 1 is novel over Tyrell et al. for similar reasons to those set forth above with respect to the Krzysik reference. More particularly, Tyrell et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Additionally, it cannot be assumed that these limitations are inherent in the compositions of Tyrell et al. For example, Tyrell et al. state that the compositions disclosed therein comprise from about 10 to about 90 weight percent of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature, as one example of a suitable hydrophilic solvent. See Tyrell et al. at p. 14, ¶105. The compositions of Tyrell et al. may thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 90 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature). The compositions of Tyrell et al. can thus not be said to inherently (i.e., necessarily) comprise no more than about 50% (by weight) of components that are liquid at room temperature.

Furthermore, it cannot be assumed that the limitation "at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C," is inherent in Tyrell et al. Similar to the Krzysik reference discussed above,

KCC 4979
K-C 19,378A
PATENT

simply stating that the compositions disclosed therein have a melting point of from about 45°C to about 80°C, does not mean that it is inherent that at least about 85% (by weight) of the components of the compositions form a single phase at the composition's melting point. Thus, Tyrell et al. fail to disclose, either explicitly or inherently, compositions wherein at least about 85% (by weight) of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C.

Since Tyrell et al. fail to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 1, Tyrell et al. fail to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Tyrell et al. reference.

Claims 2-4, 8-10, 12-13, 15-17, 21-22, and 25-30 depend directly or indirectly from claim 1. As such, claims 2-4, 8-10, 12-13, 15-17, 21-22, and 25-30 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 31 is similar to claim 1 and is patentable over the Tyrell et al. reference for the same reasons as claim 1 set forth above as well as for the additional elements it requires.

Claims 34-35, 39-41, 43-46, 50-54, and 57-59 depend directly or indirectly from claim 31. As such, claims 34-35, 39-41, 43-46, 50-54, and 57-59 are patentable for the same

KCC 4979
K-C 19,378A
PATENT

reasons as claim 31 set forth above, as well as for the additional elements they require.

4. Rejection of Claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, and 57-59 Under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1-10, 12-13, 15-22, 25-31, 34-41, 43-54, and 57-59 under 35 U.S.C. §102(b) as being anticipated by Krzysik et al. (WO 00/64409).

Claim 1 is discussed above.

Krzysik et al. ('409) disclose skin barrier enhancing tissue products that comprise a lipid-enriched hydrophilic lotion composition. The composition may comprise from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol (having a molecular weight of about 720 or greater), from about 1 to about 30 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol, from about 0.5 to about 30 weight percent of humectant, from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent sterol or sterol derivative, and from about 0.1 to about 30 weight percent of natural fats or oils. The compositions have a penetration hardness of from about 5 to about 360 millimeters and a melting point of from about 30°C to about 100°C.

Claim 1 is novel over Krzysik et al. ('409) for similar reasons to those set forth above with respect to the Krzysik ('075) and Tyrell et al. references. More particularly, Krzysik et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are

KCC 4979
K-C 19,378A
PATENT

solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Additionally, it cannot be assumed that these limitations are inherent in the compositions of Krzysik et al. Similar to Krzysik ('075), Krzysik et al. ('409) state that the compositions disclosed therein comprise from about 10 to about 95 weight percent of a hydrophilic solvent, and list low molecular weight polyethylene glycols, defined as having molecular weights of less than 720 and liquid at room temperature, as one example of a suitable hydrophilic solvent. See '409 at p. 10, lines 335-337. The compositions of '409 may thus comprise more than 50% by weight components that are liquid at room temperature (i.e., may comprise up to 95 wt.% of low molecular weight polyethylene glycols, which are liquid at room temperature). The compositions of Krzysik et al. can thus not be said to inherently (i.e., necessarily) comprise no more than about 50% (by weight) of components that are liquid at room temperature.

Furthermore, similar to the analysis of Krzysik ('075) and Tyrell et al., it cannot be assumed that the limitation "at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C," is inherent in Krzysik et al. ('409), based on the disclosure in Krzysik et al. ('409) of compositions that have melting points that fall within the range of about 45°C to about 80°C. As noted above, Krzysik et al. ('409) state that the compositions disclosed therein have a melting point of from about 30°C to about 100°C. However, the

KCC 4979
K-C 19,378A
PATENT

Krzysik et al. ('409) reference, like Krzysik ('075) discussed above, defines "melting point" as "the temperature at which the majority of the melting occurs, it being recognized that melting actually occurs over a range of temperatures" (see '409, p. 15, lines 497-499). As such, the disclosure in Krzysik et al. ('409) of the melting point of the compositions merely means that the majority of the composition has melted at that temperature; there may, however, still be portions of the composition that have not melted (i.e., solid portions) in the composition, even at the melting temperature. Thus, it cannot be assumed that at least about 85% (by weight) of the components of the compositions will form a single phase at the composition's melting point. The '409 reference thus fails to disclose, either explicitly or inherently, compositions wherein at least about 85% (by weight) of the components of the composition form a single phase at a temperature of from about 45°C to about 80°C.

Additionally, Applicant notes that the specific formulations set forth in the Examples of Krzysik et al. ('409) either lack entirely one or more of the components of the composition of claim 1 and/or comprise amounts of one or more component that fall outside of the claimed ranges. For example, Formulas 1-5 set forth in the examples of Krzysik et al. ('409) (which appear to comprise 88-90% or more water) do not comprise an immobilizing agent in an amount of from about 30% (by weight) to about 90% (by weight), as required by claim 1. Formula 6 does not comprise from about 1% (by weight) to about 20% (by weight) of a humectant, as required by claim 1.⁴

⁴ As noted above with regard to Krzysik ('075), propylene glycol is listed in the specification of the present application as a suitable humectant, as well as a compatibilizing agent. As such, when determining the total amount of

KCC 4979
K-C 19,378A
PATENT

Since Krzysik et al. ('409) fail to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C as required in claim 1, Krzysik et al. fail to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Krzysik et al. reference.

Claims 2-10, 12-13, 15-22, and 25-30 depend directly or indirectly from claim 1. As such, claims 2-10, 12-13, 15-22, and 25-30 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

Claim 31 is similar to claim 1 and is patentable over the Krzysik et al. reference for the same reasons as claim 1 set forth above as well as for the additional elements it requires.

Claims 34-41, 43-54, and 57-59 depend directly or indirectly from claim 31. As such, claims 34-41, 43-54, and 57-59 are patentable for the same reasons as claim 31 set forth above, as well as for the additional elements they require.

5. Rejection of Claim 32 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claim 32 under 35 U.S.C. §103(a) as being unpatentable over Krzysik et al. ('409).

Claim 32 depends directly on claim 31, which is discussed

humectant in Formula 6 of the Examples of Krzysik et al. ('409), the amount of propylene glycol should also be considered. The total amount of humectant

KCC 4979
K-C 19,378A
PATENT

above. Claim 31 is patentable for the reasons set forth above. In particular, the Krzysik et al. reference fails to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has failed to meet its burden under number (1) and/or (2) above, as Krzysik et al. fail to show each and every limitation of Applicants' invention and there is no motivation or suggestion to modify Krzysik et al. to arrive at each and every limitation.

As noted above, Krzysik et al. fail to disclose a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Further, Krzysik et al. fail to suggest or disclose any motivation to one skilled in the art to modify its lipid-enriched hydrophilic

in Formula 6 thus exceeds 20 wt.% (i.e., 35% propylene glycol and 5%

KCC 4979
K-C 19,378A
PATENT

lotion composition to comprise a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

The Krzysik et al. reference fails to provide a reason why one skilled in the art would choose to use components in their compositions that would provide for no more than about 50% (by weight) of the components being liquid at room temperature and no less than about 50% of the components being solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. Specifically, nowhere is there motivation or suggestion to such components. Furthermore, as noted above, the Krzysik et al. reference teaches the preferred hydrophilic solvent, which makes up 10% to 95% by weight of their compositions, to be low molecular weight polyethylene glycols having molecular weights of less than 720 and being liquids at room temperature. As such, one skilled in the art would not, and could not, be motivated to look to the components of the compositions of the Krzysik et al. reference to arrive at the compositions of Applicant's claim 31.

There is simply no motivation to modify the Krzysik et al. reference to arrive at claim 31, and claim 32, which depends on claim 31, cannot be said to be obvious in view of the cited reference.

glycerin).

KCC 4979
K-C 19,378A
PATENT

6. Rejection of Claims 23-24 and 55-56 Under 35 U.S.C.

§103(a)

Reconsideration is requested of the rejection of claims 23-24 and 55-56 under 35 U.S.C. §103(a) as being unpatentable over Krzysik et al. in view of Elias et al. (U.S. 5,643,899).

Claims 23-24 and 55-56 depend from claims 1 and 31, respectively. As such, claims 23-24 and 55-56 are patentable over Krzysik et al. for the same reasons as claims 1 and 31 set forth above. Specifically, Krzysik et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

Elias et al. fail to overcome the above shortcoming. Specifically, Elias et al. disclose topical formulations for repairing the epidermal barrier function. Specifically, the formulations contain various combinations of lipids selected from the three major epidermal lipid classes (i.e., ceramides, cholesterol, and free fatty acids) or their structurally similar precursors, isomers, or analogs.⁵ Specifically preferred embodiments of the lipid formulations include: (1) a two-component combination of cholesterol and acylceramide; (2) a three-component combination of cholesterol, acylceramide, and one or more fatty acids of 12-20 carbon atom length; (3) four-component combination of cholesterol, ceramide, essential fatty acid, and non-essential or bulk fatty acids of 12-20 carbon atom

⁵ See Elias et al. at col. 1, ln. 50-54 and col. 4, ln. 53-56.

KCC 4979
K-C 19,378A
PATENT

lengths; (4) combinations of (1) and (2) with the acylceramide replaced by a glycoceramide; (5) combinations of (1), (2), (3), or (4) with petrolatum, glycerin, or both added; and (6) a glycoceramide or acylglycoceramide with trehalose as the glyco moiety.⁶

Significantly, nowhere in Elias et al. is it disclosed to use a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. As such, claims 23-24 and 55-56 are patentable over Krzysik et al. in view of Elias et al.

7. Rejection of Claims 14 and 33 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 14 and 33 under 35 U.S.C. §103(a) as being unpatentable over Krzysik et al. in view of Mitchnick et al. (U.S. 6,103,267).

Claims 14 and 33 depend from claims 1 and 31, respectively. As such, claims 14 and 33 are patentable over Krzysik et al. for the same reasons as claims 1 and 31 set forth above. Specifically, Krzysik et al. fail to disclose or suggest a composition wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C.

⁶ *Id.* at col. 5, ln. 18-55.

KCC 4979
K-C 19,378A
PATENT

Mitchnick et al. fail to overcome the above shortcoming. Specifically, Mitchnick et al. disclose a non-aqueous dispersion of hydrophilic particles that contain stabilized ascorbic acid, which is useful in the cosmetic, dermatological and/or veterinary fields. Specifically, in one embodiment, the dispersion comprises a non-aqueous phase containing particles comprising a water-soluble polymer, such as vitamins, anti-inflammatory agents, anesthetics, analgesics, enzymes, etc.⁷, ascorbic acid, and water (e.g., aqueous phase). The particles of the dispersion have a number average diameter of less than 2 microns. The dispersion of Mitchnick et al. can further comprise a surface active agent for stabilizing the dispersion. Specifically, in one particularly preferred embodiment, the dispersion is a water-in-silicone dispersion comprising from about 0.1% to about 10% surface active agent for dispersing the discontinuous phase into the continuous silicone phase.

Significantly, nowhere in Mitchnick et al. is it disclosed that the dispersion comprises no more than about 50% (by weight) components being liquid at room temperature and no less than about 50% components being solid at room temperature, and wherein at least about 85% (by weight) of the components of the dispersion form a single phase at a temperature of from about 45°C to about 80°C. As such, claims 23-24 and 55-56 are patentable over Krzysik et al. in view of Mitchnick et al.

8. Rejection of Claims 1-59 for Obviousness Type Double Patenting

Claims 1-59 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting

⁷ See Mitchnick et al. at col. 3, ln. 37-44 and col. 4, ln. 37-39.

KCC 4979
K-C 19,378A
PATENT

as being unpatentable over claims 1-30 and 32-60 of co-pending U.S. Patent Application No. 10/659,969 and claims 1-59 of co-pending U.S. Patent Application No. 10/659,862.

Applicants respectfully call the Office's attention to MPEP §804, I.B.1., which notes that if "provisional" obviousness-type double patenting rejections in two or more applications are the only rejections remaining in those applications and all applications are filed on the same day, the examiner should determine which application claims the base invention and which application(s) claims the improvement (added limitations). The obviousness-type double patenting rejection in the base application can be withdrawn without a terminal disclaimer, while the obviousness-type double patenting rejection in the improvement application(s) cannot be withdrawn without a terminal disclaimer. The present application and co-pending Application Nos. 10/659,969 and 10/659,862 were all filed on September 11, 2003. As this provisional rejection is not the only rejection in the present application, Applicants would like to delay responding to this rejection. If the Office has any questions please contact Mr. Christopher M. Goff at 314-231-5400.

Even if upon entry of this Amendment A, the 102(b) and 103(a) rejections are overcome (which Applicants believe that they have) and the provisional obviousness-type double patenting rejection is the only rejection remaining in the present application, the present rejection is premature. As stated in MPEP §804, I.B.1., since it is not evident which of the pending applications the Office would determine to be the "base application," any action with regard to the present rejection is premature, until such a determination has been made.

KCC 4979
K-C 19,378A
PATENT

9. Rejection of Claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 for Obviousness-type Double Patenting over U.S. Patent No. 5,869,075

Reconsideration is requested of the rejection of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 under the judicially created doctrine of obviousness-type double patenting in view of claims 16-33 of U.S. Patent No. 5,869,075 ('075). In particular, the Office has stated that the claims of the instant application are not patentably distinct from the claims of '075 because while '075 does not claim the instant composition having the specific combination of from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) of an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent, and wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, independent claim 16 (of '075), and its dependent claims, claim similar components, and therefore, similar subject matter.

Applicants respectfully submit that the subject matter of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 of the instant application would not have been obvious in view of claims 16-33 of '075. The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. §103 obviousness determination. However, a

KCC 4979
K-C 19,378A
PATENT

distinction applies: a rejection for obviousness-type double patenting must be grounded on a comparison of the claimed invention to the claims in the cited patent; the disclosure of the cited patent may not be used as prior art.

In the instant case, the Office appears to state that the composition as claimed in claims 16-33 of '075 comprise the same or a slight variation of the composition of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 of the present application, and as such, similar compositions and therapeutic results by the instantly claimed compositions of the present invention would have been expected by those of ordinary skill. This, however, is clearly not the case.

As noted above, by requiring the presently claimed moisturizing and lubricating composition to include no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature, the composition provides sufficient plasticity to help avoid products that are too hard, brittle, or flaky, while preventing the components of the composition from migrating away from the surface of a substrate to which the composition is applied. Nothing in claims 16-33 of '075 state that their composition should comprise no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature. More importantly, there is no recognition in the claims of '075 or otherwise of the advantages of such a composition, and nothing to suggest that the compositions of '075 would inherently have such a makeup.

Furthermore, as claimed in claim 17 of '075, the hydrophilic solvents can include 30% (by weight) to about 90%

KCC 4979
K-C 19,378A
PATENT

(by weight) low molecular weight polyethylene glycol, and as noted above, as defined in '075, low molecular weight polyethylene glycols are liquid at room temperature. As such, the compositions as claimed in '075 may comprise more than 50% (by weight) of components that are liquid at room temperature (i.e., may comprise up to 90% (by weight) low molecular weight polyethylene glycols, which are liquid at room temperature). Moreover, the Office has offered no convincing line of reasoning as to why a person of ordinary skill in the art would conclude that the compositions as claimed in '075 would require no more than about 50% (by weight) of components that are liquid at room temperature.

As such, the moisturizing and lubricating compositions of the present application are patentably distinct from the compositions claimed in '075. Applicants thus respectfully submit that the nonstatutory obviousness-type double patenting rejection over U.S. Patent No. '075 is improper, and request withdrawal of this rejection.

10. Rejection of Claims 1, 4-10, 13, 15-17, 21-22, and 25-30 for Obviousness-type Double Patenting over U.S. Patent No. 6,475,197

Reconsideration is requested of the rejection of claims 1, 4-10, 13, 15-17, 21-22, and 25-30 under the judicially created doctrine of obviousness-type double patenting in view of claims 1-43 of U.S. Patent No. 6,475,197 ('197). In particular, the Office has stated that the claims of the instant application are not patentably distinct from the claims of '197 because although the instant claims are directed to a composition and the claims of '197 are directed to absorbent products, the claims are

KCC 4979
K-C 19,378A
PATENT

obvious over each other since the absorbent product of '197 could comprise the instantly claimed moisturizing and lubricating composition.

Applicants respectfully submit that the subject matter of claims 1, 4-10, 13, 15-17, 21-22, and 25-30 of the instant application would not have been obvious in view of claims 1-43 of '197.

Specifically, '197 claims a body facing material having an outer surface, wherein the outer surface of the body facing material has a composition that enhances skin barrier. The composition consists of: from about 10 to about 90 weight percent hydrophilic solvent; from about 5 to about 95 weight percent high molecular weight polyethylene glycol having a molecular weight of about 720 or greater; from about 1 to about 30 weight percent of a C₁₄ to C₃₀ or greater fatty alcohol; from about 0.5 to about 10 weight percent of humectant; from about 1 to about 20 weight percent of oil-in-water emulsifying surfactant having an HLB range greater than 7; from about 0.1 to about 20 weight percent of sterol or sterol derivative; and from about 0.1 to about 30 weight percent of natural fats or oils.

In the instant case, the Office appears to state that the absorbent products as claimed in claims 1-43 of '197 comprise the same or a slight variation of the composition of claims 1-10, 12-13, 25-32, 34-41, 43, and 52-59 of the present application, and as such, similar compositions and therapeutic products incorporating the instantly claimed compositions of the present invention would have been expected by those of ordinary skill. This, however, is clearly not the case.

As noted above, by requiring the presently claimed moisturizing and lubricating composition to include no more than

KCC 4979
K-C 19,378A
PATENT

about 50% (by weight) of components that are liquid at room temperature and no less than about 50% (by weight) of components that are solid at room temperature, the composition provides sufficient plasticity to help avoid products that are too hard, brittle, or flaky, while preventing the components of the composition from migrating away from the surface of a substrate to which the composition is applied. Nothing in claims 1-43 of '197 state that their absorbent products should comprise a composition having no more than about 50% (by weight) of components that are liquid at room temperature and no less than about 50% of components that are solid at room temperature. More importantly, there is no recognition in the claims of '197 or otherwise of the advantages of using such a composition, and nothing to suggest that the compositions used in the absorbent products of '197 would inherently have such a makeup.

Furthermore, as claimed in claim 1 of '197, the compositions can include 10% (by weight) to about 90% (by weight) hydrophilic solvents. One particularly preferred hydrophilic solvent is a low molecular weight polyethylene glycol, and as defined in '197, low molecular weight polyethylene glycols are liquid at room temperature. As such, the compositions used in the articles as claimed in '197 may comprise more than 50% (by weight) of components that are liquid at room temperature (i.e., may comprise up to 90% (by weight) low molecular weight polyethylene glycols, which are liquid at room temperature). Moreover, the Office has offered no convincing line of reasoning as to why a person of ordinary skill in the art would conclude that the compositions as claimed in '197 would require the composition to include no more than about 50% (by weight) of components that are liquid at room

KCC 4979
K-C 19,378A
PATENT

temperature and no less than about 50% (by weight) of components that are solid at room temperature.

As such, the moisturizing and lubricating compositions of the present application are patentably distinct from the compositions used in the absorbent products as claimed in '197. Applicants thus respectfully submit that the nonstatutory obviousness-type double patenting rejection over U.S. Patent No. '197 is improper, and request withdrawal of this rejection.

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fees in connection with this Amendment A to Deposit Account Number 19-1345 in the name of Senniger Powers.

Respectfully submitted,

/Christopher M. Goff/

Christopher M. Goff, Reg. No. 41,785
SENNIGER POWERS
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
(314) 231-5400

CMG/JMB/dhm

Via EFS